REMARKS

Claims 1, 3-10, 19-23, and 27-36 are pending in the application. By the present amendment, claims 1, 4, 7, and 9 are hereby amended. Support for the amendment of claims 1 and 7, which recite "for 4 weeks or more" is provided by paragraph 11 of the application. Support for the amendment of claims 4 and 9, which recite "about 45 °C to about 120 °C" is provided by paragraph 24 of the application. Accordingly, the amendment of claims 1, 4, 7, and 9 does not add new matter. In view of the amendments and following remarks, Applicants respectfully request reconsideration of claims 1, 3-10, 19-23, and 27-36.

CLAIM REJECTIONS - 35 USC §103

Claims 1, 3-10, 19-23, and 27-36 are rejected under 35 USC §103(a) as being unpatentable over Killion (U.S. Patent No. 6,022,371) in view of Lafont *et al.* (U.S. Patent No. 5,957,975). Applicants respectfully traverse the rejection.

The Examiner has asserted that Killion discloses "heating a polymeric cylindrical device ... to a temperature sufficiently above the glass transition temperature of the polymer and for a time sufficient to erase memory of previous processing of the device," making reference to column 3, lines 39-45 of Killion, which describes heat setting a stent at about 510 °C for about 2 minutes. However, as explained by Dr Tahmer Sharkawi in the enclosed Declaration, a bioresorbable polymer cannot be subjected to the conditions described in Killion without burning (i.e., thermally degrading) the polymer. In fact, Dr. Sharkawi provides data showing that a variety of bioresorbable polymers will all decompose at temperatures ranging from 235 °C to 400 °C. The data on the decomposition of biodegradable polymers can be obtained from the four additional references enclosed with this response, as indicated in the Declaration. The inability of a bioresorbably polymer to withstand the conditions described by Killion is further supported in the Declaration by an experiment demonstrating that a bioresorbable polymeric stent subjected to these conditions was completely destroyed.

In order to anticipate the elements of a claim, a reference must be enabling. See *Chester v. Miller*, 906 F.2d at 1576 n.2, 15 U.S.P.Q.2d at 1336 n.2 (Fed. Cir. 1990). Killion teaches that polymer stents can be used, and teaches heat setting a stent made of a metallic alloy. However, Killion does not provide an enabling disclosure for heating a bioresorbable polymeric cylindrical

device, which is required by all of the present claims. Because Killion does not teach or suggest heating a bioresorbable polymeric cylindrical device at a temperature that would enable the memory of previous processing to be erased, without destroying the polymer, it does not teach "heating a polymeric cylindrical device ... to a temperature sufficiently above the glass transition temperature of the polymer and for a time sufficient to erase memory of previous processing of the device" as required by the present claims.

Lafont *et al.* does not rectify this deficiency of Killion. Lafont *et al.* discloses "heating a stent for a time sufficient to render the stent more malleable" (column 8, lines 14-35) in order to keep the stent in place around a balloon mounted on a catheter. Lafont *et al.* also discloses heating a stent for 30 seconds or less to again make it more malleable before expansion of the stent (column 9, lines 16-28). However, the declaration by Dr. Sharkawi states that it would be clear to one skilled in the art that (even) 2 minutes is not sufficient time to erase the memory of previous processing of the device. Accordingly, merely rendering a stent more malleable, or heating it for 30 seconds or less, is not sufficient to erase the memory of previous processing of the device. Lafont *et al.* therefore does not disclose heating a polymeric cylindrical device ... to a temperature sufficiently above the glass transition temperature of the polymer and for a time sufficient to erase memory of previous processing of the device, as required by the claims. Accordingly, because neither Killion nor Lafont *et al.* disclose heating a polymeric cylindrical device as claimed, this element of the claims is not provided by either reference and the claims are therefore not obvious over Killion in view of Lafont *et al.*

The claims of the present invention also require rapidly cooling the bioresorbable polymeric cylindrical device at a temperature below the Tg of the polymer to quench the polymeric cylindrical device and to provide an educated polymeric cylindrical device having a memory of the final predetermined diameter. The Examiner has asserted that this aspect of the claims is provided by column 3, lines 45-49 of Killion, which states that the stent is "cooled or allowed to cool." Applicants respectfully disagree that Killion teaches rapid cooling, because cooling at a rapid rate is not disclosed.

Killion further does not teach "rapidly cooling [...] below the Tg of the polymer to quench the polymeric cylindrical device and to provide an educated [...] device". Nowhere does Killion refer to quenching or a glass transition temperature (Tg). As explained by Dr

Sharkawi, this is because the teaching of Killion is directed to a locking stent made of a metal alloy (Nitinol™) and not of a polymer. The step described in Killion can thus in no way be assimilated to the "quenching step of the educating procedure" according to the present invention.

Combination of Killion with Lafont *et al.* in no way rectifies the deficiencies of Killion with regard to rapid cooling to a temperature below the glass transition temperature. While Lafont *et al.* does disclose two heating steps used to render the stent more malleable, the nature of cooling for the first heating step is only described as "cool[ing] to room temperature" (column 8, line 32) and is not described at all with regard to the second heating step. Accordingly, because neither Killion nor Lafont *et al.* disclose rapidly cooling the polymeric cylindrical device as claimed, this element of the claims is not provided by either reference and the claims are therefore not obvious over Killion in view of Lafont *et al.*

The Examiner also asserts that while Killion teaches mounting the device on an inflatable balloon catheter, it does not teach reducing the diameter of the cylindrical device by heating the device to a temperature at or above the Tg of the polymer while evenly applying pressure to the exterior surface of the wall of the device, and then rapidly cooling the device below the Tg to provide an assembly comprising an inflatable balloon catheter and an expandable polymeric stent which is substantially resistant to negative recoil when expanded mechanically, but that Lafont *et al.* provides the lacking elements and that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the methods of Killion with the methods of LaFont *et al.* to keep the stent in place on the balloon. Applicants respectfully disagree.

At the outset, Applicants note that Killion does not teach mounting the device on an inflatable balloon catheter. The locking stent described in Killion is instead mounted on a delivery catheter that incorporates a pull back sheath (see column 3, lines 50-53). The use of a balloon catheter is only considered in Killion when a further expansion of the Killion stent is desired once the stent (already in an open, expanded position) is located on the target position in the vasculature. Specifically, Killion states that "the stent delivery catheter may then be removed and if desired a balloon catheter may be used to further expand locking stent 10. This process of tacking up the locking stent 10 with a balloon may be useful in situations where portions of the vasculature will not allow all of the arms 15 to engage the appropriate notch 17" (column 3, lines

61-66). Killion thus does not teach mounting an educated polymeric cylindrical device on an inflatable balloon, as required by the claims, but rather merely discloses subsequent insertion of a balloon catheter to further expand an already-inserted stent in some situations.

Because Killion does not teach insertion of the stent on a balloon catheter, there would be no motivation to modify Killion by the methods of Lafont *et al.*, which provides a method for mounting a stent onto a balloon catheter. The motivation to combine with Lafont *et al.* is further diminished by the fact that the stent described in Killion is a self-expanding stent. Expansion of the stent of Killion is initiated by withdrawing the pull back sheath that is placed over the stent before insertion on the stent delivery catheter. There is thus no reason to deliver the stent of Killion on a balloon catheter, because mechanical expansion, such as that provided by a balloon catheter, is not required by a self-expanding stent. Because there is no motivation to combine Lafont *et al.* with Killion, and the Examiner has used the asserted motivation to reject Applicants' claims under 35 U.S.C. §103, the claims are not obvious over Killion in view of Lafont *et al.*

Accordingly, for at least the reasons provided herein, Killion and Lafont *et al*, either alone or combined, do not render any of the claims in the instant application obvious, and Applicants respectfully request that the rejection of the claims under 35 U.S.C. §103(a) be withdrawn.

Applicants submit that claims 1, 3-10, 19-23 and 27-36 are in condition for allowance. Prompt notice of such allowance is respectfully requested. If the Examiner has any questions regarding the claims, he is encouraged to contact the undersigned at the phone number listed below.

Respectfully submitted,

Date: 12/9/08

By: _____

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Enclosures:
Declaration of Dr. Sharkawi under 37 CFR §1.132
References 1-4, referred to in Dr. Sharkawi's Declaration